IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION	**MDL No. 2445**
THIS DOCUMENT RELATES TO:,	**Master File No. 2:13-MD-2445-MSG**
Wisconsin, et al v. Indivior Inc. et al.	Case No. 2:16-cv-5073-MSG
STATE OF WISCONSIN By Attorney General Brad D. Schimel, *et al.*, Plaintiffs, v. INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC.; *et al.*, Defendants.	**Civ. A. No. 2:16-cv-5073-MSG**

MEMORANDUM IN SUPPORT OF INDIVIOR INC.'S MOTION TO DISMISS

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I. INTRODUCTION

The State plaintiffs' First Amended Complaint bears many similarities to those filed earlier in the *Suboxone* litigation, including the complaints examined in detail in this Court's Memorandum Opinion of December 3, 2014 (ECF 97). All plaintiffs allege that Indivior Inc., the manufacturer of Suboxone medications, engaged in a "product hop" by marketing a new formulation – Suboxone Film – that was not interchangeable, at least under certain states' laws, with the older Suboxone Tablet formulation or generic alternatives to Suboxone Tablets. All plaintiffs also allege that Indivior attempted to delay the regulatory approval of generic products, first by allegedly not cooperating in the development of a joint "REMS" safety program, and then by filing a Citizen Petition that plaintiffs deem to be a sham.

However, in the two years since the Court wrote its Memorandum Opinion, new appellate guidance has become available. In particular, the Third Circuit rejected a "product hop" claim in *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016) ("*Doryx*"). In addition, the Third Circuit examined the need to show foreclosure of competition in another case involving competition in the pharmaceutical markets, and the Second Circuit affirmed the dismissal of an antitrust claim which, like the one before this Court, alleged without supporting facts that the filing of a citizen petition delayed generic entry. *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394 (3d Cir. 2016); *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51 (2d Cir. 2016).

The States' complaint is also set apart from the others because the States, even more than the other plaintiffs, rely on an extreme view of competition policy at odds with both the pro-competitive goals of the antitrust laws and the pro-innovation goals of the Hatch-Waxman Amendments. The States seem to view drug markets as a government-mandated cartel, where brand manufacturers hold monopolies until their exclusivities expire, and are then obligated to

surrender their sales to the generic companies without making any attempt to compete. The States would simply outlaw the development of new products. They thus allege that it was wrongful "to develop a new version of Suboxone," and to convince people to buy it. States Am. Compl. ¶ 45. In an *antitrust* suit, where the States purport to be motivated by a desire to reduce the cost of medicines (*id.* ¶ 124), the States perversely allege that it was wrongful for Indivior to offer discounts (*id.* ¶ 22), and that it is a crime that Indivior "provided qualified individuals with free or low cost drugs." *Id.* ¶ 83. The States demand for themselves the right to decide which medicines their citizens should rely upon. Their preferred outcome is increased sales of generic tablets, and they claim injury from the fact that so many patients and physicians chose, and continue to choose, Film over alternative products. *See id.* ¶¶ 6, 119, 124.

The States may wish to favor generic drugs over brand-name competitors, but the antitrust laws have no such preference. As the Third Circuit explained this May, "our concern is not about which products a consumer chooses to purchase, but about which products are reasonably available to that consumer." *Eisai*, 821 F.3d at 403. After all, "[t]he antitrust laws are concerned with the protection of competition, not competitors." *Id.* at 398-99 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). Thus the focus of rule-of-reason antitrust cases is on whether competitors are foreclosed from the market, not on whether their attempts to compete are successful. "For example, if customers are free to switch to a different product in the marketplace but choose not to do so, competition has not been thwarted – even if a competitor remains unable to increase its market share." *Id.* at 403. An antitrust claim only arises where "the defendant's anticompetitive conduct rendered [consumers' choices] meaningless." *Id.* at 404.

In passing the Hatch-Waxman Amendments, Congress fully supported the right of brand-name manufacturers to develop new formulations of their medicines. One of the Act's primary purposes was to "incentivize drug manufacturers to invest in new research and development …." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 242-43 (3d Cir. 2016). Accordingly, Congress granted reformulations such as Suboxone Film an entitlement to three years of exclusivity – three years during which, even in the absence of a patent, generics are prohibited from the market. 21 U.S.C. § 355(j)(5)(F)(iii).

Consistent with these principles, this September the Third Circuit affirmed summary judgment for defendants in a product-hop case involving the drug Doryx. Although the Third Circuit did not rule out the *possibility* that "product hopping under certain circumstances may be viewed as anticompetitive," no such claim can ever arise unless the generic competitors have been "foreclosed from the market." *Doryx*, 838 F.3d at 438. Moreover, a "product hop" by itself is of no consequence to the antitrust laws; although the defendants in Doryx implemented *four* separate product hops for the express purpose (the courts assumed) of reducing generic sales (*id.* at 431, 439 & n.80), the resulting "record [was] void of any evidence of anticompetitive conduct." *Id.* at 440. As this Court indicated in its Memorandum Opinion (ECF 97 at 18-21), the focus of a so-called "product hop" case must be on coercion and market foreclosure. The Third Circuit did not have to decide precisely when, if ever, a new product introduction would constitute an antitrust violation. But to even "present a closer call," a plaintiff must show "extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer's version of a drug." *Doryx*, 838 F.3d at 440-41.

The States, however, wrote their Amended Complaint (served on November 16, 2016), as if the Third Circuit had never written the *Doryx* opinion (and for that matter, as if this Court had

never written its Memorandum Opinion). The States omit necessary allegations of foreclosure, including the "price disconnect" allegations that the Court twice found to be a necessary element of the Class Plaintiffs' product hop claims. *See* ECF 97 at 21-22; ECF 266 (Mem. Op. regarding "downstream discovery") at 6-7, 11.

The States' new allegations of a product-hop conspiracy between Indivior and a new defendant, MonoSol, are deficient for the same reason, as well as others. As shown below, (1) these parties are legally incapable of entering an antitrust conspiracy because MonoSol acted simply as a contractor with no independent presence in the market, and (2) the conspiracy described is nothing more than agreements to engage in permissible procompetitive conduct relating to bringing the new Film product to market.

Lastly, the States' delay claims should also be dismissed. The allegations regarding the REMS negotiations are identical to claims that the Court has already dismissed. ECF 97 at 24-29. The States also failed to allege facts showing that the Citizen Petition had any effect on the timing of generic entry. Although this conclusion is contrary to the Court's earlier ruling (*see id.* at 32-34), Indivior respectfully requests that the Court revisit its prior ruling in light of more recent appellate precedent. *See Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59-62 (2d Cir. 2016).

The States' state-law claims fail for the same reasons as their federal-law claims. As discussed in more detail in Section IV of Reckitt Benckiser Healthcare (UK) Limited's brief, "since Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims [should] also [be] dismissed." *See In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003).

II. THE STATES' ALLEGATIONS

A. The Product Hop and Conspiracy Claims

Defendant Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc., *see* States Am. Compl. ¶ 11) pioneered the use of buprenorphine to help treat addiction to heroin and other opioids. *See id.* ¶¶ 2, 33. When Indivior was first developing its buprenorphine products, entering such a market was considered risky – so much so that in 1994 FDA made a formal determination that Indivior was "not reasonably expected to recover the costs of developing and marketing the treatment drug from sales in the United States." *Id.* ¶¶ 35-37. To reward Indivior for taking this risk, FDA designated Indivior's original buprenorphine products, including Suboxone Tablets, as "orphan drugs." *Id.* ¶ 36. As a result of this designation, Indivior held the exclusive right to sell buprenorphine products for opioid addiction treatment from 2002, when Suboxone Tablets were first marketed, until October 8, 2009. *Id.* ¶ 37.

Generic competition could have arrived at any point following expiration of the orphan drug exclusivity in 2009; no patent protected Suboxone Tablets. States Am. Compl. ¶¶ 33, 39. Indivior anticipated intense competition from generic products and looked for a way to compete against them. *Id.* ¶ 42. Defendant MonoSol Rx LLC was offering "a unique, patent-protected delivery technology." *Id.* ¶ 48. Adopting this technology permitted Indivior "to introduce products that are highly differentiated from other dosage forms, both in performance and marketability." *Id.* Together, Indivior and MonoSol invented, patented, and obtained regulatory approval for Suboxone Film, which Indivior launched in 2010. *Id.* ¶¶ 47, 52, 55, 60, 61.

Film quickly became the most prescribed buprenorphine product (*id.* ¶ 87), a result that the States largely attribute to price discounts, providing free or low-cost drugs to needy patients, and intensive marketing efforts. *Id.* ¶¶ 77, 83. "By mid-2012, the Film accounted for over 70 percent of Suboxone prescriptions." *Id.* ¶ 87.

Though Suboxone and other buprenorphine products have a vital role in combating opioid dependency (*see id.* ¶ 2), these products are associated with safety risks. Too often, small children ingest buprenorphine products prescribed for others. Such "pediatric exposures" are medical emergencies; many have resulted in hospitalizations of young children, some of whom have died. Indivior believes that much of this harm can be avoided by packaging each dose in unit-dose child-resistant packaging, instead of using bottles containing up to 30 tablets per bottle. Suboxone Tablets were packaged in bottles. *Id.* ¶ 76. Suboxone Film employs unit-dose child-resistant packaging, which as the States admit, resulted in an "increase in safety." *Id.* ¶ 75.

In September 2012 Indivior announced that it "intended to withdraw the Tablets within the next six months," and it "also sought a declaration from the FDA that Suboxone Tablets were being voluntarily pulled from the market … due to safety issues." *Id.* ¶¶ 81-82, 102. The States allege that Indivior justified both actions by claiming a "pediatric exposure safety issue." The States also levy the false accusation that Indivior "was aware that its assertion of pediatric safety concerns regarding the tablet formulation were unfounded." *Id.* ¶¶ 81-82.

The first generic alternatives to Suboxone Tablets obtained FDA approval in February 2013, and were launched that March. States Am. Compl. ¶¶ 114, 115. The States allege that as a result of this competition, Film's market share dropped from 85% to 68%. *See id.* ¶¶ 22, 87.

When a generic product is "AB-rated" to a branded product, in many circumstances "a pharmacist may (and often must) substitute an AB-rated generic drug for a prescribed brand name drug." *Id.* ¶¶ 32, 116. The generic products that entered the market in 2013 were "AB-rated" to Suboxone Tablets, but not to Suboxone Film. *Id.* ¶ 56. As a result, when patients hand pharmacists prescriptions for Film, pharmacists dispense Film, rather than a generic product that

the doctor had not prescribed and that the patient might not want. *See id.* The States refer to the resulting sales as "ill-gotten gains." *Id.* ¶ 122.

B. The Delay Claims

Like the other plaintiffs, the States allege that Indivior delayed generic competition through two mechanisms: failing to cooperate in negotiating a "REMS" safety plan, and filing a Citizen Petition that asked FDA to mandate that all manufacturers of buprenorphine products undertake specified measures to protect children's safety.

FDA requires every manufacturer of a buprenorphine product to implement a Risk Evaluation and Mitigation Strategy ("REMS"). This REMS is essentially a commitment to take specific steps to monitor, assess, and attempt to prevent certain known dangers relating to buprenorphine, including pediatric exposure and abuse. *See* States Am. Compl. ¶¶ 57-58, 90-91.

On January 6, 2012, FDA asked Indivior to cooperate with its competitors in the creation of a shared REMS program. States Am. Compl. ¶ 91. Indivior and the generic manufacturers did not come to an agreement, and the generic manufacturers submitted their own REMS program in August 2012. *Id.* ¶ 96. The generic manufacturers, in communications with FDA, blamed Indivior, and the States uncritically adopted all of the generics' allegations. *Id.* ¶ 94.

As noted above, in September 2012, Indivior submitted a citizen petition to FDA asking, among other relief, that FDA require all manufacturers of buprenorphine products to package their products in unit-dose child-resistant packaging. The States allege that the Citizen Petition was baseless and that it had the purpose and effect of delaying FDA approval of competing generic products. *Id.* ¶¶ 98-113.

III. THE STATES' "PRODUCT HOP" CLAIMS SHOULD BE DISMISSED

This Court has twice held, and the Third Circuit has now confirmed, that foreclosure is a necessary element of a product-hop claim. *Doryx*, 838 F.3d at 438; ECF 97 at 21-22; ECF 266

(Mem. Op. regarding "downstream discovery") at 6-7, 11. But not only have the States failed to allege any facts showing that generic competitors are foreclosed from the market – they omit the "price disconnect" allegations that the Class Plaintiffs relied upon – they have also affirmatively alleged facts incompatible with its existence. Specifically, the States concede that the market is price sensitive rather than disconnected, which prevents any inference that generic manufacturers are unable to compete by offering low prices. The States also allege that generic tablets have captured more than 15% of Film's market share. States Am. Compl. ¶¶ 22, 87. To the extent the States are even attempting to allege foreclosure, they rely entirely on the lack of AB-substitution, although both this Court and the Third Circuit have held the lack of substitution to be insufficient as a matter of law to sustain a product hopping claim.

The Third Circuit has affirmed Judge Diamond's conclusion that the lack of AB-substitution is not evidence of foreclosure: "[D]octors remained free to prescribe generic [versions]; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask . . . for generic versions." *Doryx*, 2015 WL 1736957, at *13 (E.D. Pa. Apr. 16, 2015), *aff'd,* 838 F.3d 421, 441-42 (affirming "[f]or substantially the same reasons set forth in the District Court's thorough and persuasive opinion"). Indeed, in throwing out product-hop claims that were stronger than the ones presented to this Court, the Third Circuit wrote that it was "not presented with such a close call." 838 F.3d at 441.

Both the law and the operative allegations are thus different than when this Court confronted the Class Plaintiffs' theories: the States' complaint omits allegations that were crucial to the Class Plaintiffs' claims, and the Court now has the benefit of new, binding precedent. This precedent calls into question whether "product hop" claims are viable at all. *See id.* at 440 ("[W]e do not rule out *the possibility* that certain insignificant design or formula

changes, combined with other coercive conduct, could present *a closer call* with respect to establishing liability in future cases") (emphases added). But the Third Circuit left no doubt that merely introducing a non-substitutable drug does not foreclose generics from competition, and that no "product hop" claim can survive without an additional showing of foreclosure. *Id.*

A. Allegations Of Actual Foreclosure Are Necessary To State A Product-Hop Claim

As this Court previously held, "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit." ECF 97 at 18. In determining whether a showing of foreclosure is adequate to state a claim, "the test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Id.* at 21; *accord Eisai*, 821 F.3d at 403-04.

The Third Circuit, just three months ago, confirmed that proof of exclusion is indeed a necessary element of a "product hop" claim. In *Doryx*, as here, the defendant allegedly engaged in a "product hop" by making changes to an existing medicine, and then withdrawing the older version. Indeed, the *Doryx* defendants made such "hops" on four separate occasions. 838 F.3d at 431. The Third Circuit nonetheless affirmed summary judgment in favor of the defendants because the generic competitor "was not foreclosed from the market." *Id.* at 438.

Anticipating *Doryx*, this Court evaluated the Class Plaintiffs' "product hop" claims by determining whether they had alleged facts showing market foreclosure. Critical to the Court's holding that they had were the Class Plaintiffs' allegations of a "price disconnect." Generic manufacturers, once they obtained FDA approval, sold their products throughout the country,

and they were free to attempt to attract customers by charging low prices. The Class Plaintiffs argued that generic manufacturers were nevertheless effectively foreclosed because, Class Plaintiffs asserted, low prices do not affect purchase decisions in pharmaceutical markets.

> Plaintiffs assert that a disconnect exists between the person paying for the prescription and the person selecting the appropriate treatment. Due to this disconnect, the ordinary market forces that would allow consumers to consider price when selecting a product are derailed.

(ECF 97 at 21-22.)

In the Memorandum Opinion regarding downstream discovery (ECF 266), the Court eliminated any possible confusion regarding the need to plead and prove a "price disconnect." The Court noted that "these allegations are central to the product hop claim," (*id.* at 7,) and that the "product hop theory relies on the allegations that a disconnect exists." *Id.* at 6; *accord id.* at 11 ("I specifically relied on these allegations when I found that Direct Purchasers had plausibly alleged exclusionary conduct").

Accordingly, this Court's discussion in the downstream discovery opinion (which relied on Judge Diamond's *Doryx* opinion), combined with the Third Circuit's own opinion in *Doryx*, establishes that pleading a "price disconnect" is a necessary, but not sufficient, element of foreclosure. To make the necessary showing that "competition through state substitution laws is the only cost effective means of competing available to generics," (ECF 266 at 13), plaintiffs must plead and prove that price competition plays no significant role in the market for Suboxone – and thus that no generic drug is viable unless its sales arise from automatic substitution for an AB-rated product at the pharmacy.

As *Doryx* shows, moreover, the simple truism that a doctor often chooses the drug while the patient pays for it will not suffice to eliminate all other means of efficient competition. The critical inference that substitution is the "sole" efficient means cannot be drawn where, as in

Doryx, the generics entered the market and competed for sales notwithstanding the absence of automatic substitution. When the price-disconnect theory is reduced to the argument that the generics would make even more sales and profit through substitution if they did not have to face the new product, as it was in *Doryx*, no finding of foreclosure will follow. Indeed, that argument attempts to place the interest of generic competitors over competition itself – a proposition the antitrust laws fundamentally reject. *See United States v. Syufy Enterprises*, 903 F.2d 659, 668 (9th Cir. 1990) (rejecting the possibility that "efficient, aggressive competition is itself a structural barrier to entry"); *Eisai*, 821 F.3d at 398-99.

B. The States' Complaint Omits, and Is Inconsistent With, The Price-Disconnect Allegations That This Court Previously Found Central to the Product Hop Claim

Class Plaintiffs' "price disconnect" theory has fared poorly in discovery, where the record shows ample evidence of price competition. The "price disconnect" theory also failed utterly in *Doryx*, where uncontroverted evidence showed that "when Defendants increased the price of Doryx, its sales decreased, and the sales of [competing products] increased." 838 F.3d at 437. Perhaps for these reasons, the Class Plaintiffs' "price disconnect" theory does not appear anywhere in the States' 298 paragraph Amended Complaint. But regardless of *why* these allegations are absent from the States' Amended Complaint, their absence means that the States have failed to make a plausible showing of market foreclosure.

Indeed, the "price disconnect" is not just missing from the States' complaint; it is inconsistent with the States' affirmative contentions. According to the States, pricing was an integral, and effective, component of Indivior's efforts to bolster Film sales. The States alleged that Indivior effectively used pricing mechanisms including "pricing the Film so that it was less expensive than the Suboxone Tablets." States Am. Compl. ¶ 77. They further allege that Indivior "induced conversion of the market to Film by raising the price of its Suboxone Tablets

before the introduction of the AB-rated generic product into the market. As a result, the Film was initially cheaper than the branded tablets." *Id.* ¶ 84; *accord id.* ("[Indivior] also developed programs that provided discounts and rebates to consumers who purchased the Film.").

C. The Requirement Of Alleging Foreclosure Is Not Met By Allegations That Indivior Avoided State Substitution Laws

To show foreclosure in the absence of disconnect allegations, the States appear to be relying entirely upon the allegation that, by marketing Film, "Reckitt avoided, and continues to avoid, automatic substitution of AB-rated generics under state generic substitution laws …." States Am. Compl. ¶ 120. The States equate selling a non-substitutable product with "limit[ing] competition with generic substitutes for Suboxone Tablets." *Id.*

The Third Circuit, however, does not. In *Doryx*, the Third Circuit accepted plaintiffs' allegations that the defendants undertook a series of "product hops" that impaired the generics' ability to "continue to benefit from state substitution laws." 838 F.3d at 430. Notwithstanding the *Doryx* defendants' avoidance of automatic substitution, the Third Circuit found the record to be "void of any evidence of anticompetitive conduct." *Id.* at 440.

The Court has similarly rejected the theory that a generic manufacturer is foreclosed merely because it must compete against a non-substitutable product. Notwithstanding Class Plaintiffs' assertion that "the automatic generic substitution system is the only cost-efficient means of generic competition," the Court concluded that plaintiffs must still show that "the practices in question severely restricted the market," (ECF 266 at 13), since "[i]n order to establish antitrust liability, plaintiffs must prove antitrust injury …." *Id.* at 13-14.

In *Doryx*, the antitrust claims failed because – notwithstanding the lack of substitutability – the generic competitor "reaped generous profits from its sale of the generic

tablet ….” 838 F.3d at 439. Here, the States failed to even allege that the generic manufacturers of buprenorphine products did not, or could not, likewise “reap[] generous profits.”

In sum, the States failed to allege facts showing that Indivior substantially foreclosed the relevant market, omitting the “price disconnect” allegations that the Court expressly ruled were a necessary component of the “product hop” theory. Furthermore, the States have affirmatively pleaded that price competition is an effective means of shifting market share. Since these allegations are inconsistent with the “price disconnect” theory, the defects in the States’ Complaint are incurable, and their “product hop” theory should be dismissed with prejudice.

D. If State Substitution Laws Matter, Several States Lack Any Claim Because Their Laws Either Permit Tablet-Film Substitution Or Forbid It Entirely

The States’ apparent reliance on their own substitution laws dooms their Sherman Act claims in a second way. The Sherman Act must be interpreted “to have uniform nationwide application.” *Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989). Indeed, in this case, the States allege a single, uniform national market. States Am. Compl. ¶ 21. But the States’ substitution laws are not uniform.

At least six states permit pharmacists to fill Suboxone *Film* prescriptions with generic equivalents to Suboxone *Tablets*. *See* Conn. Gen. Stat. § 20–619(b) (without prescriber approval if not reasonably available for consultation); Minn. Stat. § 151.21 Subd. 3 (if “safely interchangeable” in the “pharmacist’s professional judgment,” without prescriber approval); N.J. Stat. § 24:6E-8 (if “more appropriate,” with prescriber approval); N.D. Cent. Code § 19–02.1–14.1(3) (“exercis[ing] professional judgment” without prescriber approval); Tex. Occ. Code § 562.012 (“with the patient’s consent,” without prescriber approval); Wash. Rev. Code § 69.41.130 (if equivalent in pharmacist’s judgment, with prescriber approval). In other words, in these states, substitution was never avoided.

Moreover, in at least three additional states, substitution was *never* available. Plaintiffs Oklahoma and South Carolina prohibit any substitution – even of AB-rated products – without prescriber assent. *See* Okla. Stat. tit. 59, § 353.13(D) *and* S.C. Code § 39-24-20(3). Moreover, although Plaintiff West Virginia generally permits substitution, its laws specifically prohibited "prescribing or dispensing" either Suboxone Tablets or generic alternatives to Suboxone Tablets unless Suboxone Film was "clinically contraindicated" during the relevant time period. W. Va. Code. § 60A-3-308(e) (repealed eff. June 6, 2014). The lack of automatic substitution in these states is mandated by the Plaintiff States, and cannot be blamed on Indivior.

Under the uniformity canon, such state-specific differences preclude substitution laws from supporting allegations of foreclosure in a single, nation-wide market. Accordingly, the national Sherman Act claims, as well as the state-specific claims of Connecticut, Minnesota, Oklahoma, South Carolina, Washington, and West Virginia must be dismissed.

IV. THE STATES' CONSPIRACY CLAIMS SHOULD BE DISMISSED

While the States' product-hop and delay theories differ in degree, but not kind, from those of the other plaintiffs', the States' complaint does introduce one new genus of claims – a § 1 "conspiracy" to product hop alleged against all defendants, including Indivior and MonoSol Rx LLC (which assisted Indivior in the development and manufacture of Film).[1] The conspiracy claim is defective for the same reason as the "product hop" claim: because no facts are alleged showing that the generic manufacturers are foreclosed from the market, the States cannot show harm to competition. *See Doryx*, 838 F.3d at 441 (dismissing Section 1 claims because plaintiff "failed to prove that Defendants' product hops were anticompetitive").

[1] The States also frame this claim as a § 2 conspiracy to monopolize. However, since a plaintiff cannot "succeed on [its § 2 conspiracy] claim without prevailing on its § 1 claim," *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 139 (1998), both conspiracy claims will be analyzed under the § 1 rubric.

The States' new conspiracy claim also fails for two additional, independent reasons: (1) The States fail to allege concerted action among entities that, for antitrust purposes, do not "represent[] a single enterprise," *see Siegel Transfer, Inc. v. Carrier Exp., Inc.*, 54 F.3d 1125, 1135 (3d Cir. 1995), and (2) the States likewise fail to allege facts showing that any cooperative conduct was anticompetitive. Indeed, their allegations reveal a basic misunderstanding regarding the meaning of competition.

A. The States Fail To Allege Concerted Action

The States allege that Indivior conspired with defendant MonoSol "to develop a new version of Suboxone" and then "convert the market" from Suboxone Tablets to the new Film product.[2] States Am. Compl. ¶ 45. However, because Indivior and MonoSol had a "unity of economic interest and design," they were legally incapable of conspiring. *Siegel*, 54 F.3d at 1135; *see also Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984). The allegations of the complaint show that MonoSol merely acted as a contractor, in the "joint venture to create and manufacture Suboxone Film." States Am. Compl. ¶ 12. Nowhere do the States allege that MonoSol participated in the alleged market as a seller or consumer, or otherwise had an independent competitive interest in harming Indivior's potential generic rivals. Since the joint venture between Indivior and MonoSol "does not represent a sudden joining of

[2] More specifically, the States allege a conspiracy between MonoSol and "Reckitt," and they define "Reckitt" to be an amalgam of Indivior Inc., Indivior PLC, and Reckitt Benckiser Healthcare (UK) Ltd. *See* States Am. Compl. ¶ 13. It does not appear that the States intend to allege a conspiracy among the so-called "Reckitt" entities, and in any event no such intra-corporate conspiracy is possible. Two corporations that have common ownership cannot conspire for antitrust purposes, and during the relevant time period Indivior Inc. (then known as Reckitt Benckiser Pharmaceuticals, Inc.) and Reckitt Benckiser Healthcare (UK) Ltd. were both owned by the same parent corporation (Reckitt Benckiser Group PLC). *Id.*; *Siegel*, 54 F.3d at 1133. Indivior PLC was not incorporated until 2014 (States Am. Compl. ¶ 13), and thus did not exist during the relevant time period. In any event, Indivior PLC is Indivior Inc.'s parent corporation (*id.* ¶ 11); a parent "and its wholly owned subsidiary … are incapable of conspiring with each other for purposes of § 1 of the Sherman Act." *Copperweld*, 467 U.S. at 777.

two independent sources of economic power previously pursuing separate interests, it is not an activity that warrants § 1 scrutiny." *Copperweld*, 467 U.S. at 771.

The core concern of Section 1 of the Sherman Act – the provision that prohibits conspiracies in restraint of trade – is with agreements that "deprive[] the marketplace of independent centers of decision-making that competition assumes and demands." *Id.* at 769. Section 1 does not reach agreements between contracting parties who do not have independent competitive interests in the alleged market merely because one party employed an agent, consultant, or contractor, or licensed a patent, in connection with the alleged conduct. Because such firms share a "unity of interest" or a "unity of purpose or common design," they are viewed as functionally acting as a single entity. *See id.* at 771.

Accordingly, as the Third Circuit has explained, "[c]ourts have applied [*Copperweld's*] single-entity concept to joint ventures of separately owned entities." *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 834–35 (3d Cir. 2010). The test is whether the venture "brings together the economic power of actors which were previously pursuing divergent interests and goals." *Id.* at 835.

> The relevant inquiry, therefore, is whether there is a contract, combination, or conspiracy amongst separate economic actors pursuing separate economic interests, such that the agreement deprives the marketplace of independent centers of decisionmaking, and therefore of diversity of entrepreneurial interests, and thus of actual or potential competition.

Id. The Third Circuit and others have thus rejected attempts to extend Section 1 to "agreements facilitating a restraint of trade when a party has simply entered into a permissible contract with the defendant or when the defendant has enforced a contractual right . . . ." *Harold Friedman, Inc. v. Kroger Co.*, 581 F.2d 1068, 1078 (3d Cir. 1978); *accord., e.g.*, *Siegel Transfer*, 54 F.3d 1125 (sales and management contractors).

The "single-entity concept" has been applied to strike down conspiracy allegations in the context of patent holders and their licensees, corporations and their dealers and sales agents, hospitals and their medical staffs, an alliance of hospitals, electricity distribution cooperatives, and franchisors and their franchisees.[3]

Siegel Transfer is directly on point. There, Siegel alleged that Carrier Express had conspired with Oak Management, an independent company that Carrier had hired "to handle its day-to-day operations." 54 F.3d at 1135. The Third Circuit refused to find a § 1 conspiracy for three reasons. First, "Oak Management was, in effect, an inseparable part of Carrier Express' structure." *Id.* Second, because Oak Management's "fee was a percentage of Carrier Express' revenue, Oak Management's economic well being was directly tied to Carrier Express' success." *Id.* Third, "Oak Management did not compete with Carrier Express." *Id.*

All three conditions are present here. First, the States allege that MonoSol was acting "in partnership" with Indivior in connection with a Film "joint venture." States Am. Compl. ¶¶ 12, 47. MonoSol performed an integral role in the development, approval, manufacture, and success of Suboxone Film, thus making it – as the Oak Management company was in *Siegel*, 54 F.3d at 1135 – "an inseparable part" of the Film joint venture. For example, MonoSol patented the technology that enabled Suboxone to be manufactured as a film. *Id.* ¶¶ 46, 48, 51-52. This by

[3] *Weiss v. York Hosp.*, 745 F.2d 786, 817 (3d Cir. 1984) (hospital and medical staff); *Williams v. I.B. Fisher Nevada*, 999 F.2d 445, 447 (9th Cir. 1993) (franchisors and franchisees); *City of Mt. Pleasant, Iowa v. Assoc. Elec. Co-op*, 838 F.2d 268, 274-277 (8th Cir. 1988); *Shionogi Pharma, Inc. v. Mylan, Inc.*, 2011 WL 2174499, at *5 (D. Del. May 26, 2011) (patent holder and licensee); *HealthAm. Penn., Inc. v. Susquehanna Health Sys.*, 278 F. Supp. 2d 423, 435-37 (M.D. Pa. 2003) (alliance of hospitals); *Peerless Heater Co. v. Mestek, Inc.*, 2000 WL 637082, *5-6 (E.D. Pa. May 11, 2000) (sales representatives); *Coast Cities Truck Sales, Inc. v. Navistar Int. Trans. Co.*, 912 F. Supp. 747, 765-66 (D. N.J. 1995) (dealers); *Levi Case Co. v. ATS Products, Inc.*, 788 F. Supp. 428, 430-32 (N.D. Cal. 1992) (patent holder and licensee); *N. Am. Produce Corp. v. Nick Penachio Co.*, 705 F. Supp. 746, 750 (E.D.N.Y. 1988) ("Plaintiff may be an independent businessman, but for antitrust purposes, it may be an agent.").

itself defeats the "conspiracy" claims, since "parties with unified interests, such as a patent holder and licensee, are incapable of conspiring." *Shionogi*, 2011 WL 2174499, at *5 ; *accord Levi Case Co.*, 788 F. Supp. at 430-32.

Second, as in *Siegel*, MonoSol "receive[d] royalty payments on the sales of Suboxone Film," which "further incentivized MonoSol to assist" in the success of the joint venture. States Am. Compl. ¶ 49. Just as the percentage fee in *Siegel* rendered one supposed conspirator's "economic well being … directly tied to [the other alleged conspirator's] success," *Siegel*, 54 F.3d at 1135, the States allege that the royalty payments MonoSol received induced it to "pledg[e] to do all that it can to contribute to a long and vibrant product life cycle for Suboxone Film." States Am. Compl. ¶ 85.

Third, the States do not allege that MonoSol had any independent reason to harm competition separate from the derivative benefit to its contracting principal. As in *Siegel*, MonoSol was not a competitor. Indeed, the complaint provides no reason to believe that MonoSol was (or would have been) a participant in the relevant market in *any* capacity but for its "partnership" with Indivior. "The focus of the inquiry under § 1 of the Sherman Act centers on diminution of competition that would otherwise exist." *Deutscher Tennis*, 610 F.3d at 835. No such diminution is alleged to have occurred here.

In short, MonoSol's role regarding Suboxone Film did "not suddenly bring together economic power that was previously pursuing divergent goals." *Copperweld Corp.*, 467 U. S. at 769. Accordingly, Indivior and MonoSol "constituted one economic unit," and were unable to conspire with each other as a matter of law. *Siegel*, 54 F.3d at 1135.

B. A "Conspiracy" To Innovate Is Not Anticompetitive

The States' understanding of competition, and what it means to be "anticompetitive," is exactly backwards. Marketing a new product is *encouraged* by both the antitrust laws and the

Hatch-Waxman Act. As this Court has already held, "[e]ven a monopolist may expand its market share and increase demand for its products through technological innovation, and such actions are perfectly consistent with the competitive forces that the Sherman Act was intended to foster." ECF 97 at 14 (internal quotations omitted). But it is precisely the act of bringing the new Film product to market that the States are attempting to penalize through their conspiracy claims, and no cause of action lies for a "conspiracy" to engage in benign conduct.

The States summarize their conspiracy allegations in paragraph 45 of the complaint:

> The first step of the plan was to develop a new version of Suboxone [Film] which could be used to secure patent protection. The second step was to convert the market … from Suboxone Tablets to [Film].

States Am. Compl. ¶ 45. Neither that summary paragraph, nor any other, links the agreements with MonoSol to any potentially coercive or deceptive conduct. There is no allegation that Indivior's decision to withdraw the tablets was the product of an agreement with MonoSol, nor that they agreed upon what marketing claims Indivior would make, nor that they agreed upon any other alleged conduct that purportedly "coerced" consumers. The "conspiracy" alleged is simply a conspiracy to develop and market Suboxone Film.

But the development of a new product is a *procompetitive* act. "A monopolist, no less than any other competitor, is permitted and indeed encouraged to compete aggressively on the merits, and any success it may achieve solely through the process of invention and innovation is necessarily tolerated by the antitrust laws." *Allied Orthopedic Appliances Inc. v. Tyco Healthcare Group LP*, 592 F.3d 991, 998 (9th Cir. 2010). "[A]n efficient, vigorous, aggressive competitor is not the villain antitrust laws are aimed at eliminating." *Syufy*, 903 F.2d at 669.

Indeed, this Court has already held that "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct." ECF

97 at 18; *accord Doryx*, 838 F.3d at 440 ("courts should also be wary … of turning courts into tribunals over innovative sufficiency"); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) ("Courts and juries are not tasked with determining which product … is superior. Those determinations are left to the marketplace.").

To be actionable, there must be additional conduct. There must be, in the words of the Third Circuit, "extreme coercion" or perhaps "blatant misrepresentation about a generic manufacturer's version of a drug." *Doryx*, 838 F.3d at 441. No such additional conduct is alleged in connection with MonoSol or its product development contract.

Introducing new products is likewise encouraged by the Hatch-Waxman Act which, as the Third Circuit explains, "provides a regulatory framework designed in part to … incentivize drug manufacturers to invest in new research and development …." *Modafinil*, 837 F.3d at 242-43. Indeed, Hatch-Waxman contains numerous provisions that temporarily *prohibit* generic competition in order to reward new "therapeutic uses of previously approved drugs," such as new dosage forms of existing medicines. *See* 130 Cong. Rec. 24,425 (Sept. 6, 1984) (remarks of Rep. Waxman). Most significant to this case, Congress granted three years exclusivity to "nonnew chemical entities … which have undergone new clinical studies essential to FDA approval." *Id.* These provisions are currently codified at 21 U.S.C. §§ 355(c)(3)(E)(iii) and 355(j)(5)(F)(iii). FDA has determined that a new "dosage form," such as Suboxone Film, is one of the "types of changes … that would normally warrant exclusivity," 59 Fed. Reg. 50,338, 50,357 (Oct. 3, 1994). FDA accordingly granted Suboxone Film "new dosage form" exclusivity. *See* Exhibit 1 (2011 Orange Book). Congress has deemed the development of new dosage forms to be desirable activity, and courts are prohibited from "second-guessing Congress's legislative judgment." *Doryx*, 838 F.3d at 440.

The States have amply alleged facts showing that Indivior obtained MonoSol's assistance in competing against the generics through the introduction of a new Film product. The States have failed to allege, however, that MonoSol played any role in the additional conduct that would be necessary to transform the introduction of a new competitive product into an antitrust violation. The conspiracy claims should therefore be dismissed.

V. CLAIMS BASED UPON THE STATES' ALLEGATIONS THAT DEFENDANTS DELAYED GENERIC APPROVAL SHOULD BE DISMISSED

Indivior's "orphan drug" exclusivity ended on October 8, 2009, at which point FDA was free to approve generic alternatives to Suboxone Tablets. *See* States Am. Compl. ¶ 37. However, the first such generic products did not launch until March 6, 2013, and the States allege that this "delay" is attributable to defendants' supposed misconduct. *Id.* ¶¶ 4, 115.

These delay claims can be broken down into four time periods: (1) October 2009 through the end of 2011, (2) January to August 2012 (during the negotiations regarding a joint REMS safety program), (3) September 25, 2012 (when Indivior filed its Citizen Petition) through February 22, 2013 (when FDA resolved it and approved the first two generic tablets), and (4) February 22, 2013 through March 6, 2013 (from approval of the products until they launched).

A. Allegations of Delay Relating to the Years 2009-2011 Are Frivolous

The States allege that but for defendants' alleged conduct, "generic competition to Suboxone Tablets would have been available when orphan exclusivity expired in October, 2009." States Am. Compl. ¶ 119; *accord id.* ¶¶ 4, 89. This allegation is new, and entirely unfounded. No fact is alleged that would distinguish *Doryx*, 838 F.3d at 438, where "generic companies were free to engineer their own versions during that time." The Complaint does not allege that defendants did anything, until the "REMS" negotiations began in 2012, to hinder in any way the approval and launch of a generic alternative to Suboxone Tablets.

B. This Court Has Dismissed Identical REMS Allegations (Jan. - Aug. 2012)

The States allege that FDA initiated the REMS negotiations on January 6, 2012 (States Am. Compl. ¶ 91), and that Indivior's supposed "refusal to cooperate successfully delayed submission of the shared REMS until August of 2012" (*id.* ¶ 97).

The States' REMS allegations mirror the Class Plaintiffs' REMS allegations – which this Court has already found do not state a claim (ECF 97 at 24-29) – as well as Amneal's identical allegations – which are the subject of a pending motion to dismiss. This similarity is hardly surprising: Amneal is the original source for all four complaints. The States rely upon "communications to the FDA" from the generic manufacturers (States Am. Compl. ¶ 94), which is apparently the same 2012 public letter from Amneal that the Direct Purchaser Plaintiffs appended to their Complaint (Dkt. No. 47-5 at 3-5), and that both sets of Class Plaintiffs quoted extensively in their Complaint. (*See* Dkt. No. 47, ¶¶ 106-108; Dkt. No. 48, ¶¶ 53-59.)

As shown by the chart attached to this brief as Exhibit 2, all complaints' REMS claims share the same basic allegations: FDA ordered Indivior to cooperate with its competitors to develop a joint REMS program, Indivior did not want to participate in the negotiations, Indivior's true motives were to delay generic approval, Indivior "feigned cooperation" and otherwise disguised its true motives, and Indivior took unreasonable positions in order to delay resolution – but despite Indivior's supposed intransigence, the generics submitted and obtained approval for their own REMS program, without Indivior's help. States Am. Compl. ¶¶ 91-97.

This Court has already dismissed these REMS claims because "[t]he antitrust laws do not create a duty for competitors to work together." ECF 97 at 26 (citing *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004) and *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438 (2009)). Thus even assuming that "participation on [Indivior's] part would have allowed the process to move more quickly," "[t]he antitrust laws do not impose

a duty on [Indivior] to aid the generics in obtaining expeditious approval of an ANDA." *Id.* at 29. The assertion that Indivior had a regulatory duty to cooperate adds nothing, since "statutes and regulations requiring cooperation between competitors do not create an antitrust duty to deal." *Id.* at 28. Allegations that Indivior acted unreasonably are likewise insufficient, since "a monopolist 'certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous.'" *Id.* at 29 (citing *Linkline*, 555 U.S. at 450). Finally, allegations of deceptive conduct also did not undermine the Court's conclusion that the REMS claims were legally insufficient. *Id.* at 6 (describing Class Plaintiffs' allegations of "Feigning Cooperation"); *see also, e.g.*, *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 673 (D.C. Cir. 2005) (allegations of a "Sham, 'Feel Good' Negotiation Strategy" and a failure "to bargain in good faith" with competitors were dismissed since such allegations merely restated allegations that defendant refused to cooperate).

On the same facts that the States allege in their complaint (and Amneal in its), the Court dismissed the Class Plaintiffs' REMS claims No principled argument supports a different result.

C. The Citizen Petition Allegations (Sept. 2012 – Feb. 2013) Are Inconsistent With *Apotex*

The third period of alleged delay concerns Indivior's Citizen Petition. Congress prohibits FDA from delaying approval of generic drugs because of citizen petitions. 21 U.S.C. § 355(q). The States assert that FDA nonetheless delayed approval of generic alternatives to Suboxone Tablets as a result of Indivior's Citizen Petition. Although this Court's 2014 Memorandum Opinion held that the Class Plaintiffs' similar allegations should not be dismissed (ECF 97 at 32-34), we respectfully suggest that the Court would have reached a different conclusion if it had had the benefit of the Second Circuit's 2016 decision in *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51 (2d Cir. 2016), which affirmed the dismissal of comparable claims.

In *Apotex*, the Second Circuit took judicial notice of controlling regulatory guidance (attached here as Exhibit 3). The Class Plaintiffs and Amneal argued that Indivior's Citizen Petition must have delayed generic approval because the first generics were approved on the same day that the petition was resolved. However, as provided in FDA's formal "Guidance to Industry," FDA will delay responses to citizen petitions "until it issues a decision on the corresponding ANDA application," not the other way around. *Apotex*, 823 F.3d at 60. Thus, the Second Circuit instructed that § 355(q), together with FDA's implementing Guidance, "tend[] to undermine the inference . . . that when a citizen petition is denied simultaneously with the grant of an ANDA petition, the citizen petition was a sham and an anticompetitive weapon." *Id.*

The States, taking a slightly different tack (*see* States Am. Compl. ¶ 101), argue that *every* petition subject to § 355(q) delays generic competition; they argue that because § 355(q)(1)(A)(ii) permits FDA to delay an approval if "a delay is necessary to protect the public health," "the filing of a citizen petition in and of itself creates a delay insofar as the FDA must actually review the allegations in the petition." States Am. Compl. ¶ 101.

The notion that one subpart of § 355(q) necessarily causes FDA to violate the central mandate against delays is nonsensical and inconsistent with *Apotex*, which found no such inherent delay. Indeed, FDA's Guidance, on which *Apotex* relied, explains in detail how the agency has implemented the entire statute in a consistent manner. FDA quickly assesses whether any delay is necessary by conducting a "preliminary evaluation of the issues raised in the petition," and in any event "[t]he review of applications that may be affected by the petition is governed by a separate review process." *See* Ex. 3 at 8, 12.

Neither the States, nor any other plaintiff, have alleged any *fact* indicating that the filing of the Citizen Petition had any impact whatsoever on the timing of the approvals of the generic

products. No plaintiff has alleged that the generic manufacturers had submitted fully approvable applications before Indivior filed its Citizen Petition (and we know from the discovery record that they failed to do so until immediately before FDA approved the first generic products). In light of *Apotex* and the absence of plausible factual allegations, the Court should rule that plaintiffs failed to state a claim for delay during the petitioning period.

D. Allegations of Post-Approval Delays (Feb. – Mar. 2013) Are Frivolous

Although FDA approved "approved Amneal and Actavis' ANDAs [applications] for tablet sales" on February 22, 2013 (States Am. Compl. ¶ 114), they did not launch until March 6, 2013. *Id.* ¶ 115. Though the States blame Indivior for this delay, no fact is alleged indicating why such a delay should be attributed to Indivior.

VI. CONCLUSION

For the reasons stated above, the States' First Amended Complaint should be dismissed.

Dated: December 12, 2016

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION	**MDL No. 2445**
THIS DOCUMENT RELATES TO:,	**Master File No. 2:13-MD-2445-MSG**
Wisconsin, et al v. Indivior Inc. et al.	Case No. 2:16-cv-5073-MSG
STATE OF WISCONSIN By Attorney General Brad D. Schimel, *et al.*, Plaintiffs, v. INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC.; *et al.*, Defendants.	**Civ. A. No. 2:16-cv-5073-MSG**

CERTIFICATE OF SERVICE

I, Mark Lentz, do hereby certify that on this 12th day of December, 2016, I served a true and correct copy of the foregoing document upon all counsel of record via the Court's ECF system, and to lead counsel for plaintiffs via email.

/s/ *Mark R. Lentz*
Mark R. Lentz
Attorney for Defendant Indivior Inc.

Plaintiffs' Allegations Regarding Indivior's Conduct During The REMS / SSRS Negotiations

States' 1st Am. Complaint ¶ 94	EPP 1st Consol. Am. Complaint ¶¶ 54-56	Amneal Complaint
"Had no incentive or desire to enter into a shared REMS"	"intended to … delay FDA's approval of … Suboxone tablet ANDAs"	"had no intention of cooperating" (¶ 5) "never intended to comply with the SSRS mandate" (¶ 73)
"Merely feigned cooperation with the shared REMS development process"	"merely feigned cooperation with the shared REMS development process"	"falsely represented to the FDA and generic manufacturers that it would work cooperatively to develop an SSRS" (¶ 5)
"Refused to participate in meetings with the generic ANDA filers"	"refused to participate in meetings with the generic ANDA filers"	"initially declined invitations to join the meetings, even through legal counsel" (¶ 76)
"Refused to discuss any substantive issues pertaining to the shared REMS with the generic ANDA filers"	"refused to discuss any substantive issues with the generic ANDA filers pertaining to the shared REMS"	"refused to engage in any substantive discussions about the SSRS" (¶ 79)
"Placed conditions on its cooperation with the shared REMS development process that it knew the ANDA filers could not agree to"	"placed unreasonable conditions on its cooperation with the shared REMS development process that it knew the ANDA filers could not agree to"	[Made] "an unprecedented demand wholly unrelated to product safety" (¶ 78)
"Refused to share information with the generic ANDA filers regarding the existing REMS"	"refused to share information with the generic ANDA filers about the existing REMS program"	"refused to share any non-public information, documents, or even a description of its REMS program" (¶ 79)
"Raised last-minute issues to cause further delay once a shared REMS was ready to be submitted"	"raised a last-minute issue merely to cause still further delay just before a shared REMS was to be submitted"	"Two days before the scheduled submission … suddenly announced that it would not join the SSRS submission without a prescriber outreach component " (¶ 83)